CHAPTER 16

Using International Standards to Ensure Organization Compliance

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About This Chapter

International and global standards that provide requirements or give guidance on good management practice are among the standards most widely used in many organizations around the globe. Of the many standards published, a few have achieved truly global status and are now integrated with the world economy and in the organizations that use them. This chapter discusses the standards that support the management of quality:

- ISO 9000 for Quality Management Systems
- ISO 14000 for Environmental Managements Systems
- cGMPs for Pharmaceutical and Medical Device
- ISO/TS 16949: Automotive Industry
- CMMi for Software Quality
- AS9100: Aerospace

This chapter focuses on the importance of these standards as a means to ensuring the quality of products and services. We realize there are many more standards that are available for many industries. It is not our intention to single these out as the best; we have merely selected them because of their relationship to managing quality. ISO stands for International Organization for Standardization.

High Points of This Chapter

1. ISO 9000 standards have had great impact on the implementation of international trade and quality systems by organizations worldwide. The standards have been applied in a wide range of industry/economic sectors and government regulatory areas. The ISO 9000 standards deal with the management systems used by organizations to ensure quality in: design, production, delivery, and support products.
2. To maintain its registered status, the supplier organization must pass periodic surveillance audits by a registrar. Surveillance audits are often conducted semiannually. The audits may be less comprehensive than a full audit. If so, a full audit is performed every few years.
3. The ISO 14000 is a standard for an environmental management system. It is applicable to any business, regardless of size, location, or industry. The purpose of the standard is to reduce the environmental footprint of a business and to decrease the pollution and the waste a business produces.
4. cGMP refers to the Current Good Manufacturing Practice regulations enforced by the U.S. Food and Drug Administration (FDA). cGMPs provide for systems that ensure proper design, monitoring, and control of manufacturing processes and facilities.
5. CMMI stands for the Capability Maturity Model Integration and is used as a benchmark for comparison and as an aid to understanding for software development.
6. AS9100 is a widely adopted and standardized quality management system for the aerospace industry.

International Standards Overview

Standards exist principally to facilitate international trade and to avoid harming customers and society. In the prestandardization era (before 1980), there were various national and multinational standards. Standards for electrical, mechanical, and chemical process compatibility have been around for decades. Other standards such as military standards were developed for the military and other groups for the nuclear power industry, and, to a lesser extent, for commercial and industrial use. These standards have commonalities and historical linkages. However, they were often not consistent in terminology or content for widespread use in international trade. As a result, organizations were left to recreate their own standards or adapt the existing ones. This only led to even less commonality. In the 1980s as most of the organizations in the industrialized world began to improve quality and safety at record paces there became a need to fill a void. That void was a common quality management system that would be a nonbinding "contract" between the customer and the supplier. This void was filled by the ISO 176 Technical Committee in the form of the ISO 9000 set of standards. This was later followed by filling a similar void for environmental standards with ISO 14000. Many organizations globally began using these standards as a "certified" standard

for performance. Although their intent was important, the standards became more of an opportunity to get a certificate of compliance that could be used to impress customers, rather than a set of requirements that ensured that customer needs are met.

Certain industry/economic sectors then began developing industrywide quality system standards, based upon the verbatim adoption of ISO 9000, together with industrywide supplemental requirements. The automotive industry (QS 9000), the pharmaceutical and medical devices industry (cGMPs), government regulatory agencies, and military procurement agencies (AS 9100 and the Mission Assurance Provisions, MAP), are adopting this approach in many places worldwide. Even software development uses the CMMi standard of software quality created in the early 1990s at Carnegie Mellon University to ensure a common approach to manage software quality. The standards play an important—but not always understood—role in managing quality.

We will include a brief discussion on the following standards and or industry practices:

- ISO 9000 for Quality Management Systems
- ISO 14000 for Environmental Managements Systems
- cGMPs for Pharmaceutical and Medical Devices
- ISO/TS 16949: Automotive Industry
- CMMI for Software Quality
- AS9100 and MAP in the U.S. defense industry

ISO 9000 Quality Management System Standard

The ISO 9000 standards have had great impact on international trade and quality systems implementation by organizations worldwide. The international standards have been adopted as national standards by over 100 countries. They have been applied in a wide range of industry/economic sectors and government regulatory areas. ISO 9000 standards deal with management systems used by organizations to ensure quality in: design, production, delivery, and support products. The standards apply to all generic product categories: hardware, software, processed materials, and services. The complete set of ISO 9000 family of standards provides quality management guidance, quality assurance requirements, and supporting technology for an organization's quality management system. The standards provide guidelines or requirements on what features are to be present in the management system of an organization but do not prescribe how the features are to be implemented. This nonprescriptive character gives the standards their wide applicability for various products and situations. Upon implementing ISO 9000, an organization can be registered as a Certified Quality Management System.

The standards in the ISO 9000 family were created and are produced and maintained by Technical Committee 176 of the International Organization for Standardization (ISO). The first meeting of ISO/TC176 was held in 1980. ISO 8402, the vocabulary standard, was first published in 1986. The initial ISO 9000 series was published in 1987, consisting of the following:

- Fundamental concepts and road map guideline standard ISO 9000
- Three alternative requirements standards for quality assurance (ISO 9001, ISO 9002, or ISO 9003)
- Quality management guideline standard ISO 9004

Since 1987, additional standards have been published. The ISO 9000 family now contains a variety of standards supplementary to the original series. In particular, revisions of

Clause Titles	
1	Scope
2	Normative reference
3	Definitions
4	Quality system requirements
4.1	Management responsibility
4.2	Quality system
4.3	Contract review
4.4	Design control
4.5	Document and data control
4.6	Purchasing
4.7	Control of customer-supplied product
4.8	Product identification and traceability
4.9	Process control
4.10	Inspection and testing
4.11	Control of inspection, measuring and test equipment
4.12	Inspection and test status
4.13	Control of nonconforming product
4.14	Corrective and preventive action
4.15	Handling, storage, packaging, preservation and delivery
4.16	Control of quality records
4.17	Internal quality audits
4.18	Training
4.19	Servicing
4.20	Statistical techniques

Table 16.1 Clauses of ISO 9001 and Their Typical Structures

the basic ISO 9000 series, ISO 9000 through ISO 9004, were published in 1994, 2000, and, most recently, in 2008 under the name ISO 9000:2008. This section is written in relation to the 2008 revisions after an initial introduction to the original standard. Table 16.1 displays the ISO 9000:2008 list of requirements.

ISO 9000 has been adopted and implemented worldwide for quality assurance purposes in both two-party contractual situations and third-party certification/registration situations. Their use grew in the 1990s and early 2000s but has since slowed. ISO 9000 will grow again as the newest update in eight years with the release of ISO 9000:2008. The infrastructure of certification and registration bodies, accreditation bodies, course providers, consultants, and auditors trained and certified for auditing to these standards followed a similar pattern. Mutual recognition arrangements between and among nations continue to develop, with the likelihood of recognizing ISO-sponsored quality system accreditation in the near future. Periodic surveillance audits that are part of the third-party certification/registration arrangements worldwide provide continuing motivation for supplier organizations to maintain their quality systems in complete conformance and to improve the systems to continually meet their objectives for quality.

The market for quality management and quality assurance standards itself grew rapidly, partly in response to trade agreements such as the European Union (EU), the General

Agreement on Tariffs and Trade (GATT), and the North American Free Trade Association (NAFTA). These agreements all depend upon standards that implement the reduction of nontariff trade barriers. The ISO 9000 family occupies a key role in implementing such agreements.

External Driving Forces

The driving forces that have resulted in widespread implementation of the ISO 9000 standards can be summed up in one phrase: the globalization of business. Expressions such as the "postindustrial economy" and "the global village" reflect profound changes in recent decades. These changes include the following:

- New technology in virtually all industry/economic sectors
- Worldwide electronic communication networks
- Widespread worldwide travel
- Dramatic increase in world population
- Depletion of natural resource reserves, arable land, fishing grounds, and fossil fuels
- More intensive use of land, water, energy, and air
- Widespread environmental problems/concerns
- Downsizing of large organizations and other organizations, flattened organizational structure and outsourcing of functions outside the core functions of the organization
- Number and complexity of language, culture, and legal and social frameworks encountered in the global economy
- Diversity a permanent key factor
- Developing countries becoming a larger proportion of the total global economy; there are new kinds of competitors and new markets

These changes have led to increased economic competition, increased customer expectations for quality, and increased demands upon organizations to meet more stringent requirements for quality of their products.

Globalization of business is a reality even for many small- and medium-size organizations. These smaller organizations, as well as their large counterparts, now find that some of their prime competitors are likely to be based in another country. Fewer and fewer businesses are able to survive by considering only competition within the local community. This affects the strategic approach and the product planning of organizations of all sizes.

Internal Response to the External Forces

Organizations everywhere are dealing with the need to change. There is now greater focus on human resources and organizational culture and on empowering and enabling people to do their jobs. ISO 9000 implementation involves establishing policy, setting objectives for quality, designing management systems, documenting procedures, and training for job skills. All of these elements are parts of clarifying what people's jobs are.

Organizations have adopted performance excellence programs that include business process management as a means of adapting to changing customer needs. This concept is emphasized in the ISO 9000 standards. Metrics are being used increasingly to characterize product quality and customer satisfaction more effectively.

Organizations are implementing better product design and work-process design procedures, and improved production strategies. Benchmarking and competitive assessment are used increasingly.

An important question that is often asked is "In this world of rapid change, how can a single family of standards, ISO 9000, apply to all industry and economic sectors, all products, and all sizes of organizations?"

ISO 9000 standards are founded on the concept that the assurance of consistent product quality is best achieved by simultaneous application of two kinds of standards:

- Product standards (technical specifications)
- Quality system (management system) standards

Product standards provide the technical specifications that apply to the characteristics of the product and, often, the characteristics of the process by which the product is produced. Product standards are specific to the particular product: both its intended functionality and its end-use situations that the product may encounter.

The management system is the domain of the ISO 9000 standards. It is by means of the distinction between product specifications and management system features that the ISO 9000 standards apply to all industry/economic sectors, all products, and all sizes of organizations.

Distinctions between Juran Trilogy® and ISO Standards

The ISO 9000 family standards contain requirements and guidelines. ISO 9001 (versus 9002, 9003, 9004, and so on) is a requirement standard for that system. It is a quality management system model to be used for quality assurance purposes for providing confidence in product and service quality. A requirements standard becomes binding upon an organization wherever the organization:

- Is explicitly called up in a contract between the organization and its customer
- Seeks and earns third-party certification and registration

ISO 9004 is an example of a guideline standard. Guideline standards are advisory documents. They are phrased in terms of the word "should," meaning that they are recommendations.

All of the ISO 9000 family standards are generic, in the sense that they apply to any product or any organization. All of the ISO 9000 family standards are nonprescriptive in the sense that they describe what management system functions shall or should be in place; but they do not prescribe how to carry out those functions.

ISO 9004 is similar to many National Awards for Excellence in that it provides a model for organizationwide quality management. The major difference is that the National Award Criteria are business focused and the ISO 9000 standards are not. Why? Because the standards do not include many of the enablers and influencers that will assure that all processes in an organization are compliant. The standards do not include the full scope of managing for quality as defined by Dr. Joseph Juran. They were not intended to be. As a result of complaints, we often hear ISO 9000 did not do what we expected it to do, whereas others said it was great for them. The ones that stated it did not work had an expectation that the standard alone, once implemented, would guarantee improved quality and better financial performance. They were not satisfied. They also did not know that the standard does not include

provisions for these other tasks that must happen beyond the product and service production processes. If ISO 9004 were the registration standard, more organizations would see the benefit of registration. That is because ISO 9004 is a quality management system and ISO 9001 is only an assurance system (see Table 16.2). This is a subset of what is needed to manage for quality. The organizations that stated that ISO 9004 worked for them used the standard as a building block to a better system. They filled in the gaps where the standard was not designed to do. As a result, these organizations saw ISO Standards as an important part of their performance excellence program.

Juran defined the process of planning, control, and improvement as essential to manage for quality. Quality Assurance is important since it provides information on how our system is performing to plans. Quality Control as Juran described is different than Quality Assurance. Control is about what to control, Assurance is about proving that what you controlled was indeed controlled (see Figure 16.1).

One of the most pressing needs in the early years of ISO/TC176 work was to internationally harmonize the meanings of terms such as "quality control" and "quality assurance." These two terms, in particular, were used with diametrically different meanings among various nations, and even within nations. The term "quality management" was introduced into the ISO 9000 standards as the umbrella term for quality control and quality assurance. The term "quality management" was defined, included in ISO 8402, and adopted internationally. This, in turn, enabled agreement on harmonized definitions of the meanings of each of the terms "quality control" and "quality assurance."

According to ISO 9000:2008 the standards require the following before certification can take place:

> The organization shall establish, document, implement and maintain a quality management system and continually improve its effectiveness in accordance with the requirements of this International Standard.
>
> The organization shall:
>
> determine the processes needed for the quality management system and their application throughout the organization,
>
> determine the sequence and interaction of these processes,

The Prime Focus of	
Quality Management	**Quality Assurance**
• *Achieving* results that satisfy the requirements for quality	• *Demonstrating* that the requirements for quality have been (and can be) achieved
• Motivated by stakeholders *internal* to the organization, especially the organization's management	• Motivated by stakeholders, especially customers, *external* to the organization
• Goal is to satisfy *all stakeholders*	• Goal is to satisfy all *customers*
• Effective, efficient, and continually improving overall quality-related *performance* is the intended result	• *Confidence* in the organization's products is the intended result
• Scope covers all activities that affect the total quality-related *business results* of the organization	• Scope of demonstration covers activities that directly affect quality-related *process and product results*

Table 16.2 Quality Management and Quality Assurance

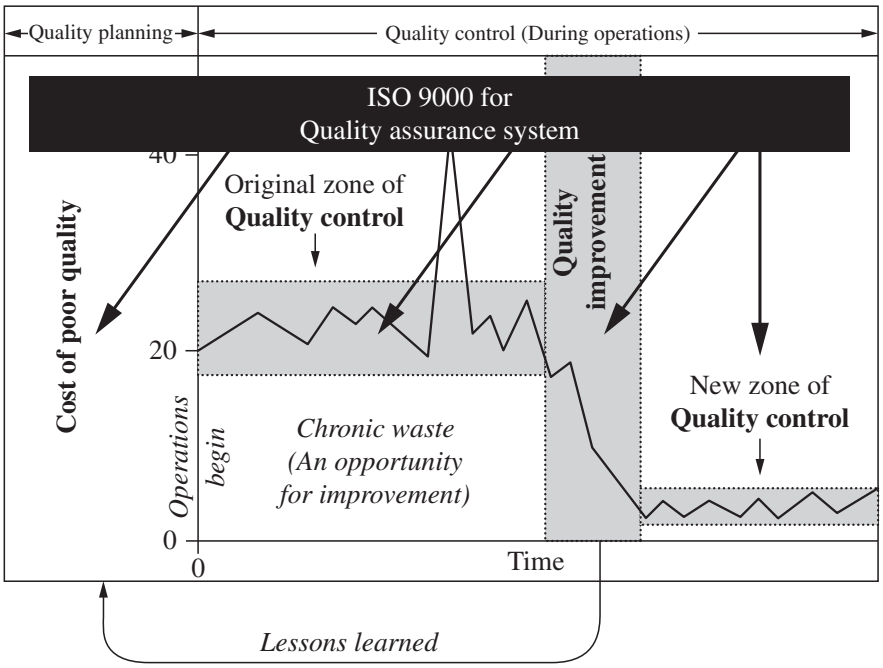

Figure 16.1 ISO 9000 and the Juran Trilogy. (*Juran Institute, Inc., Southbury CT.*)

determine criteria and methods needed to ensure that both the operation and control of these processes are effective,

ensure the availability of resources and information necessary to support the operation and monitoring of these processes,

monitor, measure where applicable, and analyze these processes, and

implement actions necessary to achieve planned results and continual improvement of these processes.

These processes shall be managed by the organization in accordance with the requirements of this International Standard. Where an organization chooses to outsource any process that affects product conformity to requirements, the organization shall ensure control over such processes. The type and extent of control to be applied to these outsourced processes shall be defined within the quality management system.

Quality System Certification/Registration

The earliest users of quality assurance requirements standards were large customer organizations such as electric power providers and military organizations. These customers often purchase complex products to specific functional design. In such situations, quality assurance requirements are called up in a two-party contract where the providing organization (i.e., the supplier) is referred to as the "first party" and the customer organization is referred to as the "second party." Such quality assurance requirements typically include provisions for the providing organization to have internal audits sponsored by its management to verify that its quality system meets the contract requirements. These are first-party audits. Such contracts typically also include provisions to have external audits sponsored by the management of the customer organization to verify that the supplier organization's quality system meets the contract requirements. These are second-party audits. Within a contractual

arrangement between two such parties, it is possible to tailor the requirements, as appropriate, and to maintain an ongoing dialogue between customer and supplier.

When such assurance arrangements become a widespread practice throughout the economy, the two-party, individual-contract approach becomes burdensome. There develops a situation where each organization in the supply chain is subject to periodic management system audits by many customers and is itself subjecting many of its subsuppliers to such audits. There is a lot of redundant effort throughout the supply chain because each organization is audited multiple times for essentially the same requirements. The conduct of audits becomes a significant cost element for both the organizations performing the audit and the organizations being audited.

Certification/Registration-Level Activities

The development of quality system certification/registration is a means to reduce the redundant, non-value-adding effort of these multiple audits. A third-party organization, which is called a "certification body" in some countries, or a "registrar" in other countries (including the United States), conducts a formal audit of a supplier organization to assess conformance to the appropriate quality system standard, say, ISO 9001 or ISO 9002. When the supplier organization is judged to be in complete conformance, the third party issues a certificate to the supplying organization and registers the organization's quality system in a publicly available register. Thus, the terms "certification" and "registration" carry the same marketplace meaning because they are two successive steps signifying successful completion of the same process.

To maintain its registered status, the supplier organization must pass periodic surveillance audits by the registrar. Surveillance audits are often conducted semiannually. They may be less comprehensive than the full audit. If so, a full audit is performed every few years.

In the world today, there are hundreds of certification bodies/registrars. Most of them are private, for-profit organizations. Their services are valued by the supplier organizations they register, and by the customer organizations of the supplier organizations, because the registration service adds value in the supply chain. It is critical that the registrars do their work competently and objectively and that all registrars meet standard requirements for their business activities. They are, in fact, supplier organizations that provide a needed service product in the economy.

Accreditation-Level Activities

To ensure competence and objectivity of the registrars, systems of registrar accreditation have been set up worldwide. Accreditation bodies audit the registrars for conformity to standard international guides for the operation of certification bodies. The quality system of the registrar comes under scrutiny by the accreditation body through audits that cover the registrar's documented quality management system, the qualifications and certification of auditors used by the registrar, the record keeping, and other features of the office operations. In addition, the accreditation body witnesses selected audits done by the registrar's auditors at the facility of the client supplier organization.

Mutual International Acceptance

Various other countries have implemented these three areas of activity, too:

1. Accreditation of certification bodies/registrars
2. Certification of auditors
3. Accreditation of auditor training courses

Various bilateral mutual recognition agreements are in place between certain countries whereby, for example, the certification of an auditor in one country carries over into automatic recognition of that certification in another country. In other situations, a memorandum of understanding has been negotiated between, say, the accreditation bodies in two countries, whereby they enter into a cooperative mode of operation preliminary to entering into a formal mutual recognition agreement. Under a memorandum of understanding, the accreditation bodies may jointly conduct the audit of a registrar, and the auditors may jointly document the results of the audit. However, each of the accreditation bodies would make its own decision whether to grant or continue the accreditation, as the case may be.

In principle, there should be no need for a supplier organization to obtain more than one certification/registration. A certificate from a registrar accredited anywhere in the world should, in principle, be accepted by customer organizations anywhere else in the world. In practice, it takes time to build infrastructure comparable in any country. It takes additional time (measured in years) for that infrastructure to mature in its operation and for confidence to build in other countries. Of course, not all countries decide to set up their own infrastructure but may choose to have their supplier organizations who wish to become registered do so by employing the services of an accredited registrar from another country.

Indeed, many registrar organizations have established operations internationally and provide services in many countries. Such registrars often seek accreditation in multiple countries because their customers (supplier organizations) look for accreditation under a system with which they are familiar and have developed confidence.

At the present time, there is a multiplicity of arrangements involving single or multiple accreditations of registrars, single or multiple certifications of auditors, and single or multiple accreditations of training courses. The overall system is moving toward widespread mutual recognition, but the ultimate test of credibility is the marketplace willingness to accept a single certification and a single accreditation.

The International Organization for Standardization (ISO), in January 1995 reaffirmed its support for the Quality System Assessment Recognition (QSAR) and approved a plan of action for setting the program in motion. This effectively laid the foundation for a voluntary system aimed at encouraging worldwide acceptance of ISO 9000 certificates.

The current status where registrars and course providers may have multiple accreditations, and auditors may have multiple certifications, may seem to have more redundancy than is necessary. If we step back and compare the current situation to the alternative of widespread second-party auditing of the quality systems of supplier organizations, it must be acknowledged that the present situation is better because there is

- Much less redundancy of auditing
- Much improved consistency of auditing
- The potential for even less redundancy and further improved consistency through the use of international standards and guides as criteria and through mutual harmonization efforts driven by the marketplace

Formal International Mutual Recognition

For the United States, there is one further complication. Almost alone among the countries of the world, the U.S. standards system is a private sector activity. The American National Standards Institute (ANSI), a private sector organization, is the coordinating body for standards in the United States. Under the ANSI umbrella, many organizations produce and maintain numbers of American national standards. Most of these standards relate to product technical specifications. Among the largest U.S. producers of standards are such organizations as the

American Society of Testing and Materials (ASTM), the American Society of Mechanical Engineers (ASME), and the Institute of Electrical and Electronics Engineers (IEEE), but there are many other organizations that produce American national standards applicable to specific products or fields of activity. The ANSI system provides a consistent standards development process that is open, fair, and provides access to all parties that may be materially affected by a standard. The success of the U.S. system is attested to by the predominance of the U.S. economy internationally and the widespread adoption of U.S. standards for multinational or international use.

However, there are three levels of activities and infrastructure in relation to conformity assessment in international trade. Two levels have already been discussed: the certification/registration level and the accreditation level. The third level is recognition. At the recognition level, the national government of country A affirms to the government of country B that A's certification and accreditation infrastructure conforms to international standards and guides. In most countries of the world where the standards system is run by a government or semigovernment agency and the accreditation activities are carried out by that agency, the recognition level is virtually automatic. In the United States, various government agencies may be called upon to provide the formal recognition.

For example, in dealing with the European Union (EU) on products that fall under one of the EU directives that regulate products that have health, safety, and environmental risks, the EU insists upon dealing through designated government channels. The relevant U.S. government agency varies from one EU directive to another. In many areas, the recognition responsibility will come under the recently authorized National Voluntary Conformity Assessment System Evaluation (NVCASE) program to be run by the Department of Commerce through the National Institute of Standards and Technology. The NVCASE program had not come into operation at the time of this writing.

Conformity Assessment and International Trade

The conformity assessment approach of the EU typifies what is happening in many parts of the world. For a regulated product to be sold in any EU country, it must bear the "CE" mark. Under the EU's modular approach, to qualify to be able to use the mark, the supplier organization must produce evidence of conformity in four areas:

1. Technical documentation of product design
2. Type testing
3. Product surveillance (by samples, or by each product)
4. Surveillance of quality assurance

Depending on the directive, the EU will offer suppliers various routes (modules) to satisfy the requirements. These routes range from "Internal Control of Production," which focuses on the product surveillance aspects, to "Full Quality Assurance," which typically focuses on certification/registration to ISO 9001 and relies upon the ISO 9001 requirements for capability in product design. In most modules, the manufacturer must submit product units, and/or product design technical information, and/or quality system information to a certification body that has been designated by the government as a "notified body." In some modules, the notified body must also provide for product tests where required. Several modules involve certification to ISO 9001, ISO 9002, or ISO 9003.

Implementing this modular approach to conformity assessment for regulated products by the European Union (then called the European Community) was the largest, single, early

impetus to the rapid spread of certification/registration to ISO 9001 or ISO 9002 worldwide. For example, about half of the dollar volume of U.S. trade with Europe is in regulated products. Nevertheless, global trends in technology and in requirements for quality, and the cost savings of third-party versus widespread second-party auditing, as discussed previously, are powerful additional incentives and staying power for sustained international use and growth of third-party quality system certification/registration.

Moreover, for a supplier organization it is not effective to attempt to have two quality management systems, one for regulated products and another for nonregulated products. Consequently, there are multiple incentives for large numbers of supplier organizations, engaged directly or indirectly in international trade, to operate a quality management system that conforms to ISO 9001 or ISO 9002, as appropriate.

Guiding Principles

There are many registrars; each is registering many supplier quality systems. Each supplier is dealing with many customers. It is impractical to adequately monitor the operations of such a system solely by periodic audits conducted by an accreditation body. Consequently, the guiding principle should be that primary reliance must be placed on the concept of "truth in labeling," by means of which every customer has routine, ready access to the information upon which to judge all four elements of the scope of a supplier's registered quality system.

ISO 14000 Environmental Management System

The ISO 14000 is a standard for an environmental management system. It is applicable to any business, regardless of size, location, or industry. The purpose of the standard is to reduce the environmental footprint of a business and to decrease the pollution and waste a business produces. The most recent version of ISO 14001 was released in 2004 by the International Organization for Standardization (ISO).

The ISO 14000 environmental management standards exist to help organizations minimize how their operations negatively affect the environment. In structure it is similar to ISO 9000 quality management, and both can be implemented side by side. In order for an organization to be awarded an ISO 14001 certificate, the organization must be externally audited by an audit body that has been accredited by an accreditation body.

An effective environmental management system that meets the requirements of ISO 14001:2004 is a management tool enabling an organization of any size or type to do the following:

- Identify and control the environmental impact of its activities, products, or services
- Improve its environmental performance on a continual basis
- Implement a systematic approach to setting environmental objectives and targets, to achieving these ends, and to demonstrating that they have been achieved.

Certification to Standard

Certification auditors need to be accredited by the International Registrar of Certification Auditors. The certification body has to be accredited by the Registrar Accreditation Board in the United States, or the National Accreditation Board in Ireland.

The ISO 14000 family addresses various aspects of environmental management. The very first two standards, ISO 14001:2004 and ISO 14004:2004, deal with environmental management systems (EMS). ISO 14001:2004 provides the requirements for an EMS, and ISO 14004:2004 gives general EMS guidelines.

Other standards and guidelines in the ISO 14000 family address specific environmental aspects, including labeling, performance evaluation, life cycle analysis, communication, and auditing.

The standards consist of the following elements:

- ISO 14001 environmental management systems—requirements with guidance for use.
- ISO 14004 environmental management systems—general guidelines on principles, systems and support techniques.
- ISO 14015 environmental assessment of sites and organizations.
- ISO 14020 series (14020-14025) environmental labels and declarations.
- ISO 14031 environmental performance evaluation—guidelines.
- ISO 14040 series (14040-14049), Life Cycle Assessment, LCA, discusses preproduction planning and environment goal setting.
- ISO 14050 terms and definitions.
- ISO 14062 discusses making improvements to environmental impact goals.
- ISO 14063 environmental communication—guidelines and examples.
- ISO 19011 specifies one audit protocol for both 14000 and 9000 series standards together. This replaces ISO 14011—how to tell if your intended regulatory tools worked. Using ISO 19011 is now the only recommended way to determine this.

How ISO 14000 Works

- ISO 14001:2004 does not specify levels of environmental performance. If it specified levels of environmental performance, they would have to be specific to each business activity and this would require a specific EMS standard for each business; that is not the intention.
- ISO has many other standards dealing with specific environmental issues. The intention of ISO 14001:2004 is to provide a framework for a holistic, strategic approach to the organization's environmental policy, plans, and actions.
- ISO 14001:2004 gives the generic requirements for an environmental management system. The underlying philosophy is that whatever the organization's activity, the requirements of an effective EMS are the same.

This establishes a common reference for communicating about environmental management issues between organizations and their customers, regulators, the public, and other stakeholders.

Because ISO 14001:2004 does not lay down levels of environmental performance, the standard can to be implemented by a wide variety of organizations, whatever their current level of environmental maturity. However, a commitment to compliance with applicable environmental legislation and regulations is required, along with a commitment to continual improvement—for which the EMS provides the framework.

ISO 14000 Standards

ISO 14004:2004 provides guidelines on the elements of an EMS and its implementation and discusses principal issues involved.

ISO 14001:2004 specifies the requirements for such an environmental management system. Fulfilling these requirements demands objective evidence that can be audited to demonstrate that the environmental management system is operating effectively in conforming to the standard.

What Can Be Achieved?

ISO 14001:2004 is a tool that can be used to meet internal objectives: to assure management that it is in control of the organizational processes and activities having an impact on the environment and to assure employees that they are working for an environmentally responsible organization.

ISO 14001:2004 can also be used to meet the following external objectives:

- Provide assurance on environmental issues to external stakeholders—such as customers and the community. Regulatory agencies comply with environmental regulations, support the organization's claims, and communicate about its own environmental policies, plans, and actions.
- Provide a framework for demonstrating conformity via suppliers' declarations of conformity, assessment of conformity by an external stakeholder—such as a business client—and for certification of conformity by an independent certification body.

Importance of ISO 14000 Standards to the Management of Quality

Chapter 2, Quality's Impact on Society and the National Culture, and Chapter 10, A Look Ahead: Eco-Quality for Environmental Sustainability, of this handbook outlined the importance of organizations meeting the expanding needs of its customers. As we move into the next decade, customers will require suppliers to demonstrate that they are actively concerned about the environment and that the products or services are produced free from environmental hazards. This will place the importance of this standard on a par with quality standards. As more customers demand confidence in an organization's ability to prove that the organization is worthy, pressure will be placed on the organizations to be certified in ISO 14000 standards. For more information on this standard, please refer to www.iso.org.

Industry-Specific Adoptions and Extensions of ISO 9000 Standards

In some sectors of the global economy, there are industry-specific adoptions and extensions of the ISO 9000 standards. These situations are a classic example of a problem opportunity. As problems, these adaptations and extensions strain the goal of nonproliferation. As opportunities, they have been found effective in a very few industries where there are special circumstances and where appropriate ground rules can be developed and implemented consistently. These special circumstances have been characterized by the following:

- Industries where the product impact on the health, safety, or environmental aspects is potentially severe; consequently, most nations have regulatory requirements regarding a supplier's quality management system
- Industries that have had well-established, internationally deployed industry-specific or supplier-specific quality system requirements documents prior to publication of the ISO 9000 standards

Fortunately, in the very few instances shown so far, the operational nonproliferation criteria of the ISO/IEC directives have been followed.

Medical Device Industry

Circumstance 1 relates to the medical device manufacturing industry. For example, in the United States, the Food and Drug Administration (FDA) developed and promulgated the Good Manufacturing Practice (GMP) regulations. The GMP operates under the legal imprimatur of the FDA regulations, which predate ISO 9000 standards. The FDA regularly inspects medical device manufacturers for their compliance with the GMP requirements. Many of these requirements are quality management system requirements that parallel the subsequently published ISO 9002:1987 requirements. Other GMP regulatory requirements relate more specifically to health, safety, or environmental aspects. Many other nations have similar regulatory requirements for such products.

In the United States, the FDA has created revised GMPs that parallel closely the ISO 9000 standard plus specific regulatory requirements related to health, safety, or the environment. Expanding the scope of ISO 9000 to include quality system requirements related to product design reflects the recognition of the importance of product design and the greater maturity of quality management practices in the medical device industry worldwide. Similar trends are taking place in other nations, many of which are adopting ISO 9001 verbatim for their equivalent of the GMP regulations.

Current Good Manufacturing Practices (cGMPs) for human pharmaceuticals affect every American. Consumers expect that each batch of medicines they take will meet quality standards so that they will be safe and effective. Most people, however, are not aware of cGMPs, or how FDA assures that drug manufacturing processes meet these basic objectives. Recently, FDA has announced a number of regulatory actions taken against drug manufacturers based on the lack of cGMPs.

What Are cGMPs?

cGMP refers to the Current Good Manufacturing Practice regulations enforced by the FDA. cGMPs provide for systems that ensure proper design, monitoring, and control of manufacturing processes and facilities. Adherence to the cGMP regulations ensures the identity, strength, quality, and purity of drug products by requiring that manufacturers of medications adequately control their manufacturing operations. This includes establishing strong quality management systems, obtaining appropriate quality raw materials, establishing robust operating procedures, detecting and investigating product quality deviations, and maintaining reliable testing laboratories. This formal system of controls at a pharmaceutical organization, if adequately put into practice, helps to prevent instances of contamination, mixups, deviations, failures, and errors. This ensures that drug products meet their quality standards.

cGMP requirements were established to be flexible in order to allow each manufacturer to decide individually how to best implement the necessary controls by using scientifically sound design, processing methods, and testing procedures. The flexibility in these regulations allows companies to use modern technologies and innovative approaches to achieve higher quality through continual improvement. Accordingly, the "C" in cGMP stands for "Current," requiring companies to use technologies and systems that are up-to-date in order to comply with the regulations. Systems and equipment that may have been "top-of-the-line" to prevent contamination, mix-ups, and errors 10 or 20 years ago may be less than adequate by today's standards.

It is important to note that cGMPs are minimum requirements. Many pharmaceutical manufacturers are already implementing comprehensive, modern quality systems and risk management approaches that exceed these minimum standards.

Why Are cGMPs Important to Software Development?

A consumer usually cannot detect (through smell, touch, or sight) that a drug product is safe or if it will work. Although cGMPs require testing, testing alone is not enough to ensure quality. In most instances, testing is done on a small sample of a batch (e.g., a drug manufacturer may test 100 tablets from a batch that contains 2 million tablets) so that most of the batch can be used for patients rather than be destroyed by testing. Therefore, it is important that drugs are manufactured under conditions and practices required by cGMP regulations to ensure that quality is built into the design and manufacturing process at every step. Facilities that are in good condition, equipment that is properly maintained and calibrated, employees who are qualified and fully trained, and processes that are reliable and reproducible are a few examples of how cGMP requirements help to ensure the safety and efficacy of drug products.

How Does the FDA Determine if an Organization Is Complying with cGMP Regulations?

The FDA inspects pharmaceutical manufacturing facilities worldwide using scientifically and cGMP-trained individuals whose job it is to evaluate whether the organization is following cGMP regulations. The FDA also relies upon reports of potentially defective drug products from the public and from the industry. The FDA will often use these reports to identify sites for which an inspection or investigation is needed. Most companies that are inspected are found to be fully compliant with the cGMP regulations.

cGMPs. In August 2002, the FDA announced the pharmaceutical cGMPs for the twenty-first Century Initiative. In that announcement, the FDA explained the agency's intent to integrate quality systems and risk management approaches into its existing programs to encourage industry to adopt modern and innovative manufacturing technologies. The cGMP initiative was spurred by the fact that since 1978, when the last major revision of the cGMP regulations was published, there have been many advances in manufacturing science and in our understanding of quality systems. In addition, many pharmaceutical manufacturers are already implementing comprehensive, modern quality systems and risk management approaches. This guidance is intended to help manufacturers implementing modern quality systems and risk management approaches to meet the requirements of the agency's cGMP regulations. The agency also saw a need to harmonize cGMPs with other non-U.S. pharmaceutical regulatory systems and with FDA's own medical device quality systems regulations. This guidance supports these goals. It also supports the objectives of the Critical Path Initiative, which intends to make the development of innovative medical products more efficient so that safe and effective therapies can reach patients sooner.

cGMPs for the twenty-first Century Initiative steering committee created a Quality System Guidance Development working group (QS working group) to compare current cGMP regulations, which call for specific quality management elements, to other existing quality management systems. The QS working group mapped the relationship between cGMP regulations (parts 210 and 211 and the 1978 Preamble to the CGMP regulations and various quality system models, such as the Drug Manufacturing Inspections Program (i.e., systems-based inspectional program), and the Environmental Protection Agency's Guidance for Developing Quality Systems for Environmental Programs, ISO Quality Standards, other quality publications, and experience from regulatory cases. The QS working group

determined that, although the cGMP regulations do provide great flexibility, they do not incorporate explicitly all of the elements that today constitute most quality management systems.

cGMP regulations and other quality management systems differ somewhat in organization and in certain constituent elements; however, they are very similar and share some underlying principles. For example, cGMP regulations stress quality control. More recently developed quality systems stress quality management, quality assurance, and the use of risk management tools, in addition to quality control. The QS working group decided that it would be very useful to examine exactly how the CGMP regulations and the elements of a modern, comprehensive quality system fit together in today's manufacturing world. This guidance is the result of that examination.

In ISO, a new technical committee, ISO/TC210, has been formed specifically for medical device systems. TC210 has developed standards that provide supplements to ISO 9001 clauses. These supplements primarily reflect the health, safety, and environment aspects of medical devices and tend to parallel regulatory requirements in various nations.

ISO/TS 16949: Automotive Industry

In the years preceding publication of the 1987 ISO 9000 standards, various original equipment manufacturers (OEMs) in the automotive industry had developed organization-specific proprietary quality system requirements documents. These requirements were part of OEM contract arrangements for purchasing parts, materials, and subassemblies from the thousands of organizations in their supply chain. The OEMs had large staffs of second-party auditors to verify that these OEM-specific requirements were being met.

Upon publication of ISO 9001:1994, the major U.S. OEMs began implementation of an industrywide common standard—QS-9000—that incorporates ISO 9001 verbatim plus industry-specific supplementary requirements. Some of the supplementary requirements are really prescriptive approaches to some of the generic ISO 9001 requirements; others are additional quality system requirements that have been agreed on by the major OEMs; a few are OEM specific.

On December 14, 2006, all QS9000 certifications were terminated. With QS9000, the middle certification between ISO 9001 and ISO/TS 16949 were no longer valid; businesses had a choice between either ISO 9001 or TS16949. QS 9000 is considered to have been superseded by ISO/TS 16949.

ISO/TS 16949:2009, in conjunction with ISO 9001:2008, defines quality management system requirements for design and development, production and, when relevant, installation and service of automotive-related products.

ISO/TS 16949:2009 applies to sites of the organization where customer-specified parts are manufactured for production and/or service.

Supporting functions, whether on-site or remote (such as design centers, corporate headquarters and distribution centers), form part of the site audit as they support the site, but they cannot obtain stand-alone certification to ISO/TS 16949:2009. ISO/TS 16949:2009 can be applied throughout the automotive supply chain.

Computer Software

The global economy has become permeated with electronic information technology (IT). The IT industry now plays a major role in shaping and driving the global economy. As in past major technological advances, the world seems fundamentally very different, and paradoxically, fundamentally the same. Computer software development occupies a central position in this paradox.

First, note that computer software development is not so much an industry as it is a discipline.

Second, many IT practitioners emphasize that computer software issues are complicated by the multiplicity of ways that computer software quality may be critical in a supplier organization's business. For example:

- The supplier's product may be complex software whose functional design requirements are specified by the customer.
- The supplier may actually write most of its software product, or may integrate off-the-shelf packaged software from subsuppliers.
- The supplier may incorporate computer software/firmware into its product, which may be primarily hardware and/or services.
- The supplier may develop and/or purchase from subsuppliers software that will be used in the supplier's own design and/or production processes of its product.

However, it is important to acknowledge that hardware, processed materials, and services often are involved in a supplier organization's business in the same multiple ways.

What, then, are the issues in applying ISO 9001 to computer software development? There is general consensus worldwide that

- The generic quality management system activities and associated requirements in ISO 9001 are relevant to computer software, just as they are relevant in other generic product categories (hardware, other forms of software, processed materials, and services).
- There are some things that are different in applying ISO 9001 to computer software.

There is at this time no worldwide consensus as to which things, if any, are different enough to make a difference and what to do about any things that are different enough to make a difference.

ISO/TC176 developed and published ISO 9000-3:1991 as a means of dealing with this important, paradoxical issue. ISO 9000-3 contains guidelines for applying ISO 9001 to the development, supply, and maintenance of (computer) software and has been useful and widely used. ISO 9000-3 offers guidance that goes beyond the requirements of ISO 9001, and it makes some assumptions about the life cycle model for software development, supply, and maintenance. In the United Kingdom, a separate certification scheme (TickIT) for software development has been operating for several years, using the combination of ISO 9001 and ISO 9003. The scheme has received both praise and criticism from various constituencies worldwide. Those who praise the scheme claim that it:

- Addresses an important need in the economy to provide assurance for customer organizations that the requirements for quality in software they purchase (as a separate product, or incorporated in a hardware product) will be satisfied
- Includes explicit provisions beyond those for conventional certification to ISO 9001 to ensure competency of software auditors, their training, and audit program administration by the certification body.
- Provides a separate certification scheme and logo to exhibit this status publicly. Critics claim that the scheme
  - Is inflexible and attempts to prescribe a particular life cycle approach to computer software development that is out of tune with current best practices for developing many types of computer software.

- Includes unrealistically stringent auditor qualifications in the technology aspects of software development, qualifications whose technical depth is not necessary for effective auditing of management systems for software development.
- Is almost totally redundant with conventional third-party certification to ISO 9001, under which the certification body/registrar already is responsible for competency of auditors. Accreditation bodies verify the competency as part of accreditation procedures.
- Adds substantial cost beyond conventional certification to ISO 9001 and provides little added value to the supply chain.

In the United States, a proposal to adopt a TickIT-like software scheme was presented to the ANSI/RAB (Registrar Accreditation Board) accreditation program. The proposal was rejected, primarily on the basis that there was not consensus and support in the IT industry and the IT-user community.

CMMI: Software and Systems Development

Another standard that has gained popularity is the Capability Maturity Model (CMM), a service mark owned by Carnegie-Mellon University (CMU) and refers to a development model elicited from actual data. The data were collected from organizations that contracted with the U.S. Department of Defense, which funded the research, and that became the foundation from which CMU created the Software Engineering Institute (SEI). Like any model, SEI is an abstraction of an existing system. Unlike many models that are derived from academia, this model is based on observation rather than on theory.

When it is applied to an existing organization's software development processes SEI allows an effective approach toward improving them. Eventually, it became clear that this model could be applied to other processes. This gave rise to a more general concept that is applied to business processes and to developing people.

CMM was originally developed as a tool for objectively assessing the ability of the processes of government contractors to perform a contracted software project. CMM is based on the process maturity framework first described in the 1989 book, *Managing the Software Process* by Watts Humphrey. It was later published in a report in 1993 (Technical Report CMU/SEI-93-TR-024 ESC-TR-93-177 February 1993, Capability Maturity Model SM for Software, Version 1.1) and as a book authored by Xiaoqing Liu et al. in 1995.

Although CMM comes from the field of software development, it is used as a general model to aid in improving organizational business processes in diverse areas; for example, in software engineering, system engineering, project management, software maintenance, risk management, system acquisition, information technology (IT), services, business processes generally, and human capital management. The CMM has been used extensively worldwide in government, commerce, industry and software development organizations.

An organization may be assessed by an SEI-authorized lead appraiser and would then be able to claim that they have been assessed as CMM level X, where X is from 1 to 5 (maturity levels). Maturity Level 1 is Initial; Maturity Level 2 is Managed; Maturity Level 3 is Defined; Maturity Level 4 is Quantitatively Managed; and Maturity Level 5 is Optimizing (read further for more explanation of the levels). Although sometimes called CMM certification, the SEI does not use this term due to certain legal implications.

In the 1970s, the use of computers became more widespread, more flexible, and less expensive. Organizations began to adopt computerized information systems, and the demand for software development grew significantly. The processes for software development were in their infancy, with few standard or "best practice" approaches defined.

As a result, growth was accompanied by growing pains: project failure was common, the field of computer science was still in its infancy, and the ambitions for project scale and complexity exceeded market capability to deliver.

In the 1980s, several U.S. military projects involving software subcontractors ran over budget and were completed much later than planned, if they were completed at all. In an effort to determine the reason for this, the U.S. Air Force funded a study at the SEI.

The Standard CMMI Appraisal Method for Process Improvement (SCAMPI) is the official SEI method that provides benchmark-quality ratings relative to CMMI models. The CMMI model is used as a "ruler" to measure an organization's process definition, as the model is a collection of process best practices assimilated into process areas. The SCAMPI appraisal methodology is used to measure how well an organization has institutionalized the process definition into their everyday way of doing business. SCAMPI appraisals are used to identify strengths and weaknesses of current processes, reveal development/acquisition risks, and determine capability and maturity level ratings. These appraisals are mostly used either as part of a process improvement program or for rating prospective suppliers. The appraisal method consists of preparation; on-site activities; preliminary observations, findings, and ratings; final reporting; and follow-up activities.

Active development of the model by SEI began in 1986 when Watts Humphrey joined the SEI at Carnegie Mellon University in Pittsburgh, Pennsylvania, after retiring from IBM. At the request of the U.S. Air Force he began formalizing his Process Maturity Framework to aid the U.S. Department of Defense in evaluating the capability of software contractors as part of awarding contracts.

In the United States and other nations, the compatibility of the ISO 9000 standard, and the ISO 14000 standard is one part of the standardization job. Implementation requires that similar harmonization and compatibility be established in each nation in the infrastructure of accreditation bodies, certification/registration bodies, and auditor certification bodies, operating under internationally harmonized guidelines. As of this writing, the ISO 14000 infrastructure is in its infancy. However, Humphrey's approach differed because of his unique insight that organizations mature their processes in stages based on solving process problems in a specific order. Humphrey based his approach on the staged evolution of a system of software development practices within an organization, rather than measuring the maturity of each separate development process independently. CMM has thus been used by different organizations as a general and powerful tool for understanding and then improving general business process performance.

The CMM model proved useful to many organizations, but its application in software development has sometimes been problematic. Applying multiple models that are not integrated within and across an organization could be costly in terms of training, appraisals, and improvement activities. The CMMI project was formed to sort out the problem of using multiple CMMs.

For software development processes, CMM has been superseded by CMMI, though the CMM continues to be a general theoretical process capability model used in the public domain.

What Is the Capability Maturity Model?

A maturity model can be used as a benchmark for comparison and as an aid to understanding; for example, for comparative assessment of different organizations where there is something in common that can be used as a basis for comparison. In the case of CMM, the basis for comparison would be the organizations' software development processes.

CMM involves the following aspects:

Maturity levels. A five-level process maturity continuum where the uppermost (fifth) level is a notional ideal state, where processes would be systematically managed by a combination of process optimization and continuous process improvement.

Key process areas. A key process area (KPA) identifies a cluster of related activities that, when performed collectively, achieve a set of goals considered important.

Goals. The goals of a KPA summarize the states that must exist for that KPA to have been implemented in an effective and lasting way. The extent to which the goals have been accomplished indicates how much capability the organization has established at that maturity level. The goals signify the scope, boundaries, and intent of each KPA.

Common features. Common features include practices that implement and institutionalize a KPA. There are five types of common features: Commitment to Perform, Ability to Perform, Activities Performed, Measurement and Analysis, and Verifying Implementation.

Key practices. Key practices describe the elements of infrastructure and practice that contribute most effectively to the implementation and institutionalization of KPAs.

Levels of the CMM

There are five levels defined along the continuum of the CMM[9], and, according to the SEI: "Predictability, effectiveness, and control of an organization's software processes are believed to improve as the organization moves up these five levels. While not rigorous, the empirical evidence to date supports this belief." The five levels are

Level 1: Chaos or Ad hoc

It is characteristic of processes at this level that they are (typically) undocumented and in a state of dynamic change, tending to be driven in an ad hoc, uncontrolled, and reactive manner by users or events. This provides a chaotic or unstable environment for the processes.

Level 2: Repeatable

It is characteristic of processes at this level that some processes are repeatable, possibly with consistent results. Process discipline is unlikely to be rigorous, but where it exists, it may help to ensure that existing processes are maintained during times of stress.

Level 3: Defined

It is characteristic of processes at this level that there are sets of defined and documented standard processes established and subject to some degree of improvement over time. These standard processes are in place (i.e., they are the as-is processes) and are used to establish consistency of process performance across the organization.

Level 4: Managed

It is characteristic of processes at this level that, using process metrics, management can effectively control the as-is process (e.g., for software development). In particular, management can identify ways to adjust and adapt the process to particular projects without measurable losses of quality or deviations from specifications. Process capability is established from this level.

Level 5: Optimized

It is a characteristic of processes at this level that the focus is on continually improving process performance through both incremental and innovative technological changes/improvements.

At maturity level 5, processes are concerned with addressing statistical common causes of process variation and changing the process (e.g., to shift the mean of the process performance) to improve process performance. This would be done at the same time as maintaining the likelihood of achieving the established quantitative process-improvement objectives.

Within each of these maturity levels are key process areas (KPAs) which characterize that level, and there are five definitions identified for each KPA:

1. Goals
2. Commitment
3. Ability
4. Measurement
5. Verification

CMM provides a theoretical continuum along which process maturity can be developed incrementally from one level to the next. Skipping levels is not allowed.

CMM was originally intended as a tool to evaluate the ability of government contractors to perform a contracted software project. It has been used for and may be suited to that purpose, but critics pointed out that process maturity according to CMM was not necessarily mandatory for successful software development. There were/are real-life examples where the CMM was arguably irrelevant to successful software development, and these examples include many companies (also called commercial-off-the-shelf or COTS firms or software package firms). Such firms would have included, for example, Claris, Apple, Symantec, Microsoft, and IBM Lotus. Though these companies may have successfully developed their software, they would not necessarily have considered or defined or managed their processes as the CMM described as level 3 or above and so would have fitted levels 1 or 2 of the model. On the face of it, this did not impede the successful development of their software.

AS9100: Aerospace Standards

AS9100 is a widely adopted and standardized quality management system for the aerospace industry. It was released in October 1999, by the Society of Automotive Engineers and the European Association of Aerospace Industries. AS9100 replaces the earlier AS9000 and fully incorporates the entirety of the current version of ISO 9000 while adding additional requirements relating to quality and safety. Major aerospace manufacturers and suppliers worldwide require compliance and/or registration to AS9100 as a condition of doing business with them.

Prior to the adoption of an aerospace specific quality standard, various corporations typically used ISO 9000 and their own complementary quality documentation/requirements, such as the Boeing Corporation's D1-9000 or the automotive Q standard. This created a patchwork of competing requirements that were difficult to enforce and/or comply with. The major American aerospace manufacturers combined their efforts to create a single, unified quality standard, resulting in AS9000. Upon the release of AS9000, companies such as Boeing stopped using their previous quality supplements in preference to compliance to AS9000.

During the rewrite of ISO 9000 for the year 2000 release, the AS group worked closely with the ISO organization. As the year 2000 revision of ISO 9000 incorporated major organizational and philosophical changes, AS9000 underwent a rewrite as well. It was released as AS9100 to the international aerospace industry at the same time as the new version of ISO 9000. AS9100 Revision C was released in January, 2009

Standardization Is Here to Stay

Standards are here to stay. Many industries are working together with various standards bodies to periodically improve their standards and mandate as many systems as possible to ensure the safety and quality of our products. For instance, a new International Standard—ISO 31000:2009, *Risk Management—Principles and Guidelines*—was developed to help

organizations manage risk effectively. ISO 31000 provides principles, framework, and a process for managing any form of risk in a transparent, systematic, and credible manner within any scope or context.

In addition, the ISO has published a standard to facilitate implementation of quality management systems, based on ISO 9001:2000, by the medical device industry. The key objectives of ISO 13485:2003 are to maximize the probability that a medical device organization will meet regulatory quality management system requirements worldwide, will provide safe and effective medical devices, and will meet customer requirements, —Ed Kimmelman, convener of the working group that developed the new standard.

ISO 13485:2003, Medical Devices—Quality Management Systems—Requirements for Regulatory Purposes, is based on quality management system requirements currently contained in medical device regulations around the world as well as those appropriate requirements contained in ISO 9001:2000. The new standard is used by organizations involved in the design, production, installation, and servicing of medical devices as well as in the design, development, and provision of related services. It can also be used by external certification bodies to assess an organization's ability to meet requirements. The new standard, which replaces ISO 13485:1996, is the work of ISO technical committee ISO/TC 210, Quality Management and Corresponding General Aspects for Medical Devices, working group WG 1, Application of Quality Systems to Medical Devices, in conjunction with members of the Global Harmonization Task Force (Study Group 3), conceived in 1992 in an effort to achieve greater uniformity between national medical device regulatory systems.

> Standardization will embrace common operational sequences, part-dimensional strategies, and guidelines for equipment use.
>
> —Barney and De Feo (2005)

Standards are becoming a way of life for global organizations. Get ready; there is more to come.

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